



UNITED STATES PATENT AND TRADEMARK OFFICE

[Handwritten signature]

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,066	08/21/2001	Darren B. Gruis	35718/237251(5718-134)	7358

826 7590 03/24/2004

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,066

Applicant(s)

GRUIS ET AL.

Examiner

Stuart F. Baum

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, and 38-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 12/17/2003 has been entered.

Claims 1-3, 6-12, and 38-47 are pending.

Claims 4-5, 13-37 have been canceled.

Claims 38-47 have been newly added.
2. Claims 1-3, 6-12, and 38-47 are examined in the present application.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

1st Written Description

5. Claims 1-3, and 6-12, remain rejected and 38-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/17/2003. Applicant's arguments filed 12/17/2003 have been fully considered but they are not persuasive.

Applicants contend that the specification provides examples of polypeptides of interest (line 28 of page 11 through line 24 of page 12)(page 10, 5th paragraph of Applicant's response). Applicants contend that the point of novelty of the present invention is not the expression of a genus of novel polypeptides of interest but rather, the reduction or elimination of the activity of proteases in the protein storage tissue (page 10, 6th paragraph).

Art Unit: 1638

The Office concurs with the Applicant that the novelty of the application is the reduction or elimination of the activity of proteases within specific tissues. And that is precisely what the written description rejection is addressing. Applicants claims are directed to a genetically modified plant to reduce or eliminate the activity of proteases in particular tissues but Applicant has not specified what type of genetic material or explicitly which genetic material is transformed into a plant. Claim 1 is drawn to a genetically modified plant. Applicant has not specified explicitly with what the plant is transformed. How is the plant genetically modified when compared to a non-genetically modified plant? The claims read on the broad genus of antisense RNA or ribozyme constructs of any sequence which may inhibit genes encoding the recited enzymes from any source and of any sequence. The claims also read on genes encoding any enzyme inhibitor protein of any source and any sequence. No conserved structural features, i.e., sequences which occur throughout the broadly claimed genus and which are correlated with the function of inhibiting particular proteases, are disclosed. See MPEP 2163, *Lilly* and the Written Description Guidelines cited previously.

2nd Written Description

6. Claims 1-3, and 6-12, remain rejected and 38-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/17/2003. Applicant's arguments filed 12/17/2003 have been fully considered but they are not persuasive.

Applicants contend that the sequences of Arabidopsis α -VPE, β -VPE, γ -VPE, ε -VPE, AP1, and AP2 proteases are described in the specification on lines 4-13 of page 7. Furthermore, the domains of these proteins that are important for their proteolytic activity are known. Applicant contends that the domains of these proteins that are important for their proteolytic activity are known. For example, vacuolar processing enzymes are members of the Peptidase C13 family of proteases and contain a conserved domain associated with protease activity. Applicant presents an alignment of 11 proteins included in the Peptidase C13 protease family, of which, α -VPE, and β -VPE from Arabidopsis and ε -VPE are included. Applicants also disclose the aspartic proteases AP1 and AP2 which are members of the eukaryotic aspartyl protease family. These two proteases contain the Pfam consensus domain characteristic of aspartyl protease activity.

The office contends that Applicant has presented alignments that demonstrate the before mentioned proteases contain a conserved domain associated with other members the Peptidase C13 protease family. But Applicants are claiming the genus of α -vacuolar processing enzymes (α -VPE), the genus of β -vacuolar processing enzymes (β -VPE), etc. Applicants have not presented a representative number of α -VPE sequences or domains that are essential to its specific function. It is not enough to present domains associated with proteases in general, but rather, domains that are specific to the particular genus Applicant is claiming. For example, one way to satisfy the written description for the genus of α -VPE's would be to present the Arabidopsis α -VPE along with α -VPE homologues from other plant species, e.g., Brassica sp. and cotton species. Another way would be to present domains that are important to α -VPE including those domains that are specific to α -VPE's.

Scope of Enablement

7. Claims 1-3, and 6-12, remain rejected and 38-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Arabidopsis* plants in which the activity of the *Arabidopsis* ϵ -vacuolar processing enzyme (ϵ -VPE) and *Arabidopsis* β -VPE are reduced does not reasonably provide enablement for claims broadly drawn to any plant that is genetically modified to reduce or eliminate the activity of any protease wherein the protease is expressed in any tissue wherein the protease can be any of the types of proteases as listed in claims 1, 11, or 38. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/17/2003. Applicant's arguments filed 12/17/2003 have been fully considered but they are not persuasive.

Applicants contend that method of genetically modifying plants to reduce or eliminate the activity of a protease are described in the specification, e.g., transposon tagging, T-DNA insertion, gene targeting, sense suppression, and antisense suppression (page 12, 5th paragraph). Applicants contend that the Bryant et al reference teaches the utilization of antisense technology (page 13, 2nd and 3rd paragraph). Applicants contend that the Martienssen reference is not applicable because the specification discloses examples in which the β -VPE and ϵ -VPE protein activity is eliminated and yet the protein inactivity was not lethal to the plants (page 13, 3rd paragraph). Applicants contend that sense suppression (co-suppression) has been successfully used to inhibit the expression of a number of plant genes along with antisense, and Applicants

Art Unit: 1638

cite a number of U.S. patents drawn to co-suppression (page 14, 1st paragraph). Applicants contend that although some experimentation may be necessary to reduce or eliminate the activity of plant α -VPE, β -VPE, γ -VPE, ϵ -VPE, AP1, and AP2, the experimentation would not be undue in view of the nature of the invention (page 15, 2nd paragraph).

The Office interprets Applicants' remarks to mean that there are a number of ways to reduce or eliminate the activity of the specified proteases and that reducing or eliminating their activity can be beneficial and useful. Applicants' claims are drawn to all plants in which at least one of α -VPE, β -VPE, γ -VPE, ϵ -VPE, AP1, and AP2 proteases are inactivated but Applicants have only disclosed two knock-out mutants of β -VPE and ϵ -VPE in Arabidopsis. Applicants contend that it would not be undue experimentation to enable the claimed invention, based on the teachings of others. Applicants have referenced other scientific disclosures including U.S. Patents as a basis for an enabling disclosure, but all of the techniques require modifications to overcome the unpredictability inherent in the processes as evidenced by the teachings of Bryant et al., wherein said techniques are not disclosed in the instant specification. The Office asserts that even though the Bryant et al reference teaches the potential of antisense technology, the reference also teaches that the technology produces unpredictable results. In addition, just mentioning potential techniques that can be used to produce the claimed invention, does not fulfill the enablement requirement. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Art Unit: 1638

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

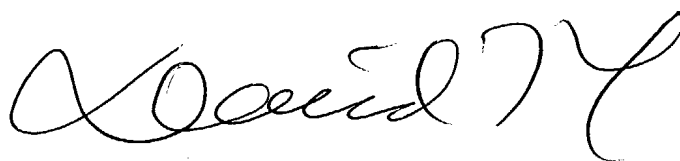
Art Unit: 1638

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
March 16, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

1638

A handwritten signature in cursive script, appearing to read "David T. Fox", written in black ink.